

KING & SPALDING

1730 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, D.C. 20006-4706
TELEPHONE: 202/737-0500
FACSIMILE: 202/626-3737

DIRECT DIAL:

May 17, 1999

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BY HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Request for Hearing: Docket No. 77N-0240 (DESI 1786)

Dear Sir/Madam:

We are writing on behalf of our client, Time-Cap Labs, Inc. ("Time-Cap Labs"), to request a hearing in the matter of Certain Single-Entity Coronary Vasodilators Containing Controlled-Release Nitroglycerin. In the Food and Drug Administration's ("FDA") notice of April 20, 1999, FDA proposes to withdraw approval of 23 new drug applications ("NDAs") and abbreviated new drug applications ("ANDAs") for these drug products. See 64 Fed. Reg. 19373.

Time-Cap Labs is the holder of ANDA 87-814, ANDA 87-815, and ANDA 87-816 for Nitro-Time (controlled-release) Capsules in three dosage strengths. All three of these ANDAs are affected by FDA's proposal.

We will submit data and information in support of this hearing request prior to the June 21, 1999 deadline.

Sincerely,


Eugene M. Pfeifer

77N-0240

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